DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-550/S-021

GlaxoSmithKline
Attention: Sherman N. Alfors, M.S.
Director, Antiviral/Antibacterial Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709-3398

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated May 6, 2003, received May 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex® (valacyclovir hydrochloride) 500 mg and 1000 mg Caplets.

This "Changes Being Effected" supplemental new drug application provides for the revision of the package insert to add tremors to the Observed During Clinical Practice subsection of the ADVERSE REACTIONS section.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 6, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Nitin Patel, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jeffrey Murray
8/8/03 08:30:27 AM